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Bristol-Myers Squibb Company

January 26, 2004

Dockets Management Branch
Food and Drug Administration, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2003N-0341; Proposed Rule, Requirements for Submission of In Vivo Bioequivalence Data *[68 Federal Register 61640 (October 29, 2003)]*

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, consumer medicines, nutritionals and medical devices. We are a leader in the research and development of innovative therapies for cardiovascular, metabolic, infectious diseases, neurological disorders, immunology, and oncology. In 2002 alone, Bristol-Myers Squibb dedicated $2.2 billion for pharmaceutical research and development activities. The company has more than 5,000 scientists and doctors committed to discover and develop best in class therapeutic and preventive agents that extend and enhance human life. Our current pipeline comprises of approximately 50 compounds under active development.

For these reasons, we are very interested in and well qualified to comment on this FDA proposal to amend its regulations on submission of bioequivalence data to require an abbreviated new drug application (ANDA) applicant to submit data from all bioequivalence studies that the applicant conducts on a drug product formulation submitted for approval.

We commend the U.S. FDA for proposing the modifications to the requirements for submission of an ANDA and agree with the FDA proposal.

Under 21 CFR 314.94(a)(7), bioequivalence information is required to ensure therapeutic equivalence between a pharmaceutically equivalent test drug product and a reference drug product. In the absence of controlled clinical safety and efficacy studies, bioequivalence data represents the primary basis to support the evaluation of the safety and efficacy of a generic product. Requiring submission of all bioequivalence studies that show that the test drug product meets and does not meet the bioequivalence criteria will provide a basis for assessing the potential for safety and/or efficacy issues associated with the ANDA product. The proposed amendment is also consistent with regulations requiring the submission of all available safety and efficacy data in an NDA (21 CFR 314.50(d)(5)(ii-iv). For these reasons, BMS supports the FDA proposal to amend the regulations as described in the Federal Register.

BMS appreciates the opportunity to provide comment and respectfully requests that FDA give consideration to our recommendations. We would be pleased to provide additional pertinent information as may be requested.

Sincerely,

Richard L. Wolgemuth

Richard L. Wolgemuth, Ph.D.
Sr. Vice President
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Bristol-Myers Squibb Company